

withdrawn from consideration subject to the restriction and election requirements and should be reconsidered when the pending claims are allowed.

II. Rejections Under 35 U.S.C. § 103(a)

Claims 1-8 and 10-29 stand rejected as allegedly prima facie obvious over the teachings of U.S. Pat. No. 6,087,509 (Claussner-'509) or U.S. Pat. No. 5,750,553 (Claussner-'553) in view of U.S. Pat. No. 5,558,859 (Cretois), in further view of U.S. Pat. No. 5,916,910 (Lai), U.S. Pat. No. 5,541,220 (Ismail), WO 92/21317 (Galey), WO 91/19701 (Dumats), and EP 427 625 (Estradier). Final Office Action at 2-4. According to the Office, neither Claussner-'509 nor Claussner-'553 "teach[es] preferred **[(A)]** film forming agents, **[(B)]** solvents, **[(C)]** plasticizers and additives." Office Action of 12/21/01 at 4. The Office, nevertheless, urges that "[i]t would have been obvious to one of ordinary skill in the art ... to modify the compositions of [either Claussner-'509 or Claussner-'553] by using the teachings of [Cretois] and obtain a composition comprising **[(D)]** a compound of] formula (I), vinylimidazolium methochloride/vinylpyrrolidone copolymer **[(a species of (A))]**, polyethoxylated hydrogenated castor oil **[(a species of (C))]**, and solvent **[(B)]**." *Id.* at 5. Applicants respectfully submit that the rejection is improper and should be withdrawn. There is no motivation to combine and/or to modify the teachings of the references, and even if combined, there is no basis on the record created by the Office to suggest finding a reasonable expectation of success.

A. The Office Admitted that the Proposed Combination Is Contrary to the Accepted Wisdom of the Art; Thus, There is No Reasonable Expectation of Success Set Forth in the Record.

Following a path discouraged in the art or proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *M.P.E.P.* § 2145 X. D 3, citing *In re*

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Hedges, 228 USPQ 685 (Fed. Cir. 1986). As admitted by the Office, the evidence of record discourages administration of antiandrogen drugs via the ineffective topical route. Final Office Action at 4. Thus, the composition proposed by the Office for such topical administration is contrary to accepted wisdom, a sign of nonobviousness. In other words, the citations of record fail to provide a factual basis for a reasonable expectation of success, as there is no basis for predicting success of a proposed combination when evidence of record discourages following the path suggested by the rejection. *M.P.E.P.* § 2143.02.

Yet, instead of withdrawing the rejection, the Office has provided an irrelevant reason for ignoring the evidence of record, and it also has improperly attempted to shift the burden of proof to Applicants. The Office's reason for ignoring the Office's acknowledged evidence of proceeding contrary to accepted wisdom is based upon a faulty premise. Citing *In re Oelrich*, 198 USPQ 210, 215 (CCPA 1978) (enclosed for consideration), the Office urges that "showings of fact are much preferred to statements of opinion." Final Office Action at 4. But here, Applicants have not relied upon opinion evidence. For example, the opinion evidence in *Oelrich* concerned opinion testimony in the form of affidavits submitted to show the level of ordinary skill in the art. *Oelrich*, 210 USPQ at 215.

In this case, unlike in *Oelrich*, there is no such analogous opinion or declaratory testimony. Here, the evidence of the knowledge of one skilled in the art are clear statements of disinterested parties in a publicly available document of record. What better evidence can there be of the knowledge of those skilled in the art? The Office's dismissal of the teachings of this document is clearly improper, absent the production of

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"facts" to show why the statements in the cited publicly available document are not what one of ordinary skill in this art would have known. *Id.*

Further, this document of record not only makes a conclusion, but it also contains factual evidence providing objective reasons supporting that conclusion, i.e., why administering antiandrogens via topical routes has been disappointing. Because the documents of record discourage administering antiandrogens via topical routes, there is no basis for a reasonable expectation of success for the Office's proposed composition, which incorporates antiandrogens of Claussner-'509 or Claussner-'553 into a topical composition. The Office has inappropriately dismissed the factual evidence of record as merely "opinion" without addressing the underlying factual basis provided in the document.

In addition to ignoring this evidence of nonobviousness, the Office also invited Applicants to submit data showing why the antiandrogens of Claussner-'509 and Claussner-'553 are not effective when topically applied. Final Office Action at 4. Yet this invitation improperly attempts to circumvent the initial burden of establishing a prima facie case of obviousness. The Office, not Applicants, has the initial burden of establishing a prima facie case of obviousness. *M.P.E.P.* § 2142. No explanation of record comes close to establishing a prima facie case of obviousness. Thus, this rejection is improper and should be withdrawn.

B. The Office Has Failed to Provide Any Basis for the Desirability of the Claimed Combination.

A prima facie case of obviousness requires not only identifying the ingredients of an invention from prior art references but also stating reasons for the desirability of their combination. *M.P.E.P.* § 2143.01-.03; *In re Kotzab*, 55 USPQ2d 1313, 1317 (Fed. Cir.

2000). In the present record, however, the Office never attempted to identify desirable reasons for combining ingredients but instead merely stated how to pick and choose compounds from the various references to recreate Applicants' invention. For example, "Claussner and Clausner disclose that their active ingredient can be incorporated with excipients...and that their compositions can be in the form of...creams [and] ointments." Final Office Action at 2 (emphasis added). Merely identifying ingredients, as the Office has done here, fails to establish a prima facie case of obviousness.

Without a doubt, the motivation to combine also requires identifying **reasons** for the **desirability** of, or in other words the motivation for, the proposed combination. *M.P.E.P.* § 2143.01. These reasons are material to patentability, and the alleged prima facie case of obviousness is improper if it is only supported by conclusory statements. *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). In this prosecution, still conspicuously absent from the Office's motivation is any desirable reason to choose the specifically proposed ingredients **(A)** to **(D)** from numerous possibilities in the disparate references to form a single composition within the scope of the claims. As the Office does not provide reasons to combine, the rejection should be withdrawn for this reason alone.

C. The Office Has Failed to Show Where the References Provide the Requisite Motivation.

The requisite motivation must be in the prior art. *M.P.E.P.* § 2143.01. Admitted by the Office, neither Claussner-'509 nor Claussner-'553 teaches the preferred film forming agents, solvents, and plasticizers. Final Office Action at 2-4. Lai, Ismail, Galey, Dumats, and Estradier were not used to remedy these deficiencies in Claussner-'509 or

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Claussner-'553. Only Cretois was cited to remedy these deficiencies of Claussner-'509 or Claussner-'553.

According to the Office, Cretois's disclosure of antisebborrhoic agents would have suggested a composition comprising **(D)** a compound of formula (I) of either Claussner-'509 or Claussner-'553, since the term antisebborrhoic agents inherently describes every member within it. *Id.* at 3. But this position is certainly unsound, because a genus describes only what one skilled in the art would at once envisage. *M.P.E.P.* § 2131.02. For example, the genus, "alkaline chlorine or bromine solution," embraces such a large number of species that one of ordinary skill in the art could not immediately envisage every species, and thus the genus fails to inherently describe the particular subgenus "alkali metal hypochlorite." *Id.* (citing *In re Meyer*, 202 USPQ 175 (CCPA 1979)).

In this case, the genus of antisebborrhoic agents is much larger than the genus of "alkaline chlorine or bromine solution," and it is also much too large for one of ordinary skill in the art to at once envisage every member of antisebborrhoic agent. Glancing at the documents of record, one can see there are at least many thousands of antisebborrhoic agents, not all of which are those of either Claussner-'509 or Claussner-'553, let alone those of the claimed invention. It defies belief that one of ordinary skill in the art would at once envisage the properties antisebborrhoic agent and thus determine which to pick and to choose for use in the invention.

As a result, some **specific** motivation to select the **claimed** species or subgenus of antisebborrhoic agent, along with the other claimed ingredients, must be taught by the prior art. Yet Cretois fails to identify any antisebborrhoic specie. The silence of


Cretois cannot provide a motivation to select any particular specie, let alone the combination of all of the various ingredients from seven difference sources in order to obtain the claimed composition. Thus, the rejection is improper and should be withdrawn.

CONCLUSION

Applicants respectfully request reconsideration and reexamination of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Enclosure: *In re Oelrich*, 198 USPQ 210 (CCPA 1978).

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